## Food and Drug Administration, HHS

due to susceptible strains of Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum, and Clostridium perfringens; dental infections due to susceptible strains of S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum, and C. perfringens; and osteomyelitis due to susceptible strains of S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum, and C. perfringens.

- (2) Cats—(i) *Amount*. 5.0 to 15.0 mg/lb body weight every 24 hours for a maximum of 14 days.
- (ii) Indications for use. For the treatment of skin infections (wounds and abscesses) due to susceptible strains of Staphylococcus aureus, S. intermedius, Streptococcus spp.; deep wounds and abscesses due to susceptible strains of Clostridium perfringens and Bacteroides fragilis; and dental infections due to susceptible strains of S. aureus, S. intermedius, Streptococcus spp., C. perfringens, and B. fragilis.

[67 FR 54954, Aug. 27, 2002, as amended at 67 FR 78684, Dec. 26, 2002; 68 FR 55824, Sept. 29, 2003; 69 FR 31734, June 7, 2004; 71 FR 39543, July 13, 2006; 72 FR 19796, Apr. 20, 2007]

## §520.452 Clenbuterol syrup.

- (a) *Specifications*. Each milliliter contains 72.5 micrograms of clenbuterol hydrochloride.
- (b) *Sponsor*. See 000010 in §510.600(c) of this chapter.
  - (c) [Reserved]
- (d) Conditions of use—(1) Horses—(i) Amount. Administer orally twice a day (b.i.d.). Initial dose is 0.5 milliliter per 100 pounds body weight (0.8 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1 milliliter per 100 pounds (1.6 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1.5 milliliters per 100 pounds (2.4 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 2.0 milliliters per 100 pounds (3.2 micrograms per kilogram) for 3 days (6 treatments). If no improvement, horse is nonresponder to clenbuterol and treatment should be discontinued.
- (ii) *Indications for use*. Indicated for the management of horses affected with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).

- (iii) Limitations. Treat at effective dose for 30 days. At the end of the 30day treatment period, drug should be withdrawn. If signs return, the 30-day treatment period may be repeated. If repeating treatment, the step-wise dosage schedule should be repeated. The effect of this drug on breeding stallions and brood mares has not been determined. Treatment starting with dosages higher than the initial dose is not recommended. Federal law prohibits the extralabel use of this drug in food animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
  - (2) [Reserved]

[63 FR 41419, Aug. 4, 1998]

## § 520.455 Clomipramine tablets.

- (a) Specifications. Each tablet contains 5, 20, 40, or 80 milligrams (mg) clomipramine hydrochloride.
- (b) Sponsor. See No. 058198 in  $\S510.600(c)$  of this chapter.
- (c) Conditions of use—(1) Amount. 2 to 4 milligrams of clomipramine hydrochloride per kilogram (0.9 to 1.8 milligrams per pound) of body weight per day, administered as a single daily dose or divided twice daily.
- (2) Indications for use. For use as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

 $[64\ FR\ 1762,\ Jan.\ 12,\ 1999,\ as\ amended\ at\ 72\ FR\ 262,\ Jan.\ 4,\ 2007]$ 

## § 520.462 Clorsulon drench.

- (a) Specifications. The drug is a suspension containing 8.5 percent clorsulon (85 milligrams per milliliter).
- (b) *Sponsor*. See No. 050604 in §510.600(c) of this chapter.
- (c) Conditions of use. Cattle—(1) Amount. One-quarter fluid ounce per 200 pounds of body weight (7 milligrams per kilogram or 3.2 milligrams per pound of body weight).
- (2) Indications for use. For the treatment of immature and adult liver fluke (Fasciola hepatica) infestations in cattle.